

BEFORE THE DEPARTMENT OF PUBLIC
HEALTH AND HUMAN SERVICES OF THE
STATE OF MONTANA

In the matter of the amendment of) NOTICE OF PUBLIC HEARING ON
ARM 37.8.1801, 37.8.1802,) PROPOSED AMENDMENT
37.8.1803, and 37.8.1808 pertaining)
to the Montana central tumor registry)

TO: All Concerned Persons

1. On December 19, 2008, at 11:00 a.m., the Department of Public Health and Human Services will hold a public hearing in the Sapphire Room of the Colonial Building, at 2401 Colonial Drive, Helena, Montana, to consider the proposed amendment of the above-stated rules.

2. The Department of Public Health and Human Services will make reasonable accommodations for persons with disabilities who wish to participate in this rulemaking process or need an alternative accessible format of this notice. If you require an accommodation, contact the Department of Public Health and Human Services no later than 5:00 p.m. on December 8, 2008, to advise us of the nature of the accommodation that you need. Please contact Gwen Knight, Office of Legal Affairs, Department of Public Health and Human Services, P.O. Box 4210, Helena, Montana, 59604-4210; telephone (406) 444-9503; fax (406) 444-9744; or e-mail dphhslegal@mt.gov.

3. The rules as proposed to be amended provide as follows, new matter underlined, deleted matter interlined:

37.8.1801 REPORTABLE TUMORS (1) through (2) remain the same.

(3) A tumor which is otherwise reportable, but has been diagnosed and recorded using the words "~~questionable~~", "~~possible~~", "~~suggests~~" or "~~equivocal~~" ~~is not considered a reportable tumor~~ "apparently", "appears", "comparable with", "compatible with", "consistent with", "favors", "malignant appearing", "most likely", "presumed", "probable", "suspected", "suspicious", or "typical of" with reference to that tumor is considered reportable.

~~(4) Whenever records of a patient with a tumor which would be reportable, if confirmed, contain the words "suspect", "probable", "suspicious", "compatible with" or "consistent with" in reference to that tumor, the tumor is considered reportable.~~

~~(5)~~ (4) In order for the department to maintain current reporting, hospitals and physicians shall submit to the department information on reportable tumors within six months from the first inpatient or outpatient date of discharge that the patient was seen with cancer; independent laboratories shall submit to the department information on reportable tumors within six months from the date the laboratory service associated with the tumor was rendered.

AUTH: 50-15-706, MCA

IMP: 50-15-703, MCA

37.8.1802 REQUIRED RECORDS, INITIAL ADMISSION AND TREATMENT

(1) Whenever a hospital initially provides medical services to any patient relating to a tumor designated as reportable by ARM 37.8.1801, it must collect, record, and make available to the department the following information about that patient:

- (a) name and current physical address of patient;
- (b) patient's physical address at time of diagnosis;
- (c) through (e) remain the same.
- (f) race, Hispanic origin if applicable, sex, and marital status ~~and religion~~ (optional);
- (g) age at diagnosis, place of birth, and month, day, and year of birth;
- (h) name, address, and phone number of friend or relative to act as contact, plus relationship of that contact to patient;
- (i) through (n) remain the same.
- (o) summary staging, including whether in situ, localized, regional, distant or unstaged, with no information, or whether AJCC or TNM staging is utilized, and, if so, the findings of this staging;
- (p) remains the same.
- (q) ~~whether American joint committee on cancer (AJCC) staging is utilized, and if so, the findings of the staging procedures done to diagnose or stage tumors including dates, procedures, and results (such as physical exams, scopes, x-rays, scans, or lab tests)~~;
- (r) cumulative summary of all therapy directed at the subject tumor, including:
 - (i) date of therapy;
 - (ii) specific type of surgery or radiation therapy, if any, and details of chemical, hormonal, or other kinds of treatment; and
 - (iii) if no therapy given, reason for lack of therapy;
- (s) status at time of latest recorded information, i.e., whether alive or dead, tumor in evidence, or recurring, or status unknown;
- (t) if recurrence of tumor, date, type, and distant sites of first recurrence;
- (u) names of physicians primarily and secondarily responsible for follow up;
- (v) date of each follow up; ~~and~~
- (w) if patient has died, date of death, place, cause, and whether autopsy performed;
- (x) primary payer at diagnosis;
- (y) usual occupation and industry; and
- (z) tobacco and alcohol use history.

AUTH: 50-15-706, MCA

IMP: 50-15-703, MCA

37.8.1803 REQUIRED RECORDS, FOLLOW UP

(1) Whenever a patient for whom information has been provided to the tumor registry is admitted to the hospital providing the information on an inpatient or outpatient basis for further treatment related to the tumor for which original registration in the tumor registry was made, the hospital must keep on file the following information:

- (a) through (h) remain the same.
- (i) if an autopsy was performed, its findings pertaining to cancer;
- (j) status at time of latest recorded information, i.e., whether alive or dead, tumor in evidence₁ or has recurred₁ or status is unknown;
- (k) if recurrence of tumor, date, type₁ and distant sites of first recurrence; and
- (l) names of those physicians primarily and secondarily responsible for follow up treatment.

AUTH: 50-15-706, MCA

IMP: 50-15-703, MCA

37.8.1808 REQUIRED RECORDS, INDEPENDENT CLINICAL LABORATORIES (1) Whenever a clinical laboratory which is not owned or operated by a hospital provides laboratory services for any patient relating to a tumor designated as reportable by ARM 37.8.1801, it must collect, record₁ and make available to the department the following information about that patient:

- (a) through (d) remain the same.
- (e) race, sex₁ and marital status;
- (f) age at diagnosis, month, day₁ and year of birth;
- (g) through (j) remain the same.
- (k) histology, including dates, place, histologic type₁ and slide number;
- (l) summary staging, including whether in situ, localized, regional, distant or unstaged, with no information, or whether AJCC or TNM staging is utilized, and, if so, the findings of the staging;
- (m) description of tumor and its spread, if any, including size in centimeters, number of positive nodes, number of nodes examined₁ and site of distant metastasis;
- (n) status at time of latest recorded information, i.e., whether alive or dead, tumor in evidence₁ or recurring₁ or status unknown; and
- (o) remains the same.

AUTH: 50-15-706, MCA

IMP: 50-15-703, MCA

4. The department has reviewed the current administrative rules pertaining to the Montana Central Tumor Registry, ARM 37.8.1801, 37.8.1802, 37.8.1803, and 37.8.1808, and has determined that the following changes need to be made.

These changes are reasonably necessary to update the Montana Central Tumor Registry reporting requirements and guidelines to be consistent with national and international standards. The changes will also allow the tumor registry to be more efficiently administered. Rationales for the specific changes are as follows:

ARM 37.8.1801(3), 37.8.1802(1)(o), and 37.8.1808(1)(l)

Conventions about reporting ambiguous terms are occasionally changed by the North American Association of Central Cancer Registries, the National Program of

Cancer Registries, and/or the World Health Organization, publisher of the International Classification of Diseases for Oncology. These rule changes will update the current version to be consistent with national and international terminology for reporting ambiguous terms.

ARM 37.8.1801(4)

The Montana Central Tumor Registry is most effective when information is as current as possible. Discharge dates may be substantially delayed relative to first contact dates and imply that the patient must have been an inpatient to be a reportable case. Adding "outpatient" to the timeframe clears this implication. This change would increase the timeliness of the data.

ARM 37.8.1802(1)(a) and (b)

Data on physical location of residence at time of diagnosis are essential to conduct many epidemiologic investigations. Physical address indicates referral patterns and allows for analysis of cancer clusters or environmental studies. Physical address allows the central registry to assign latitude and longitude to the address and gives the ability to map each location. Accurate geographic information allows a central registry to monitor cancer trends and watch for possible patterns that could be the first hint of an environmental or other geographic focus on increased cancer risk. Mailing addresses consisting of post office boxes and other nonresidential locations are not useful for these investigations. Approximately 25% of recent cases in the Montana Central Tumor Registry do not have information pertaining to the physical address.

ARM 37.8.1802(1)(f)

Requiring information on Hispanic origin would bring the Montana Central Tumor Registry into compliance with other state and federal data collection systems (e.g., birth certificates, death certificates, census, the National Program of Cancer Registries guidelines). Hispanic populations have different patterns of cancer occurrence from other populations that may also be included in the Caucasian race.

ARM 37.8.1802(1)(q)

Information previously obtained from ARM 37.8.1802(1)(q) would be obtained under ARM 37.8.1802(1)(o) in the proposed amendment. Information on procedures used to diagnose and/or stage tumors is essential for quality control and special studies. This information is needed to justify coded values in patients' cancer history, date of diagnosis, clinical findings, treatment plan, treatments provided, stage of cancer, invasion or cancer progression, and diagnostic methods.

ARM 37.8.1802(1)(t) and 37.8.1803(1)(k)

Date of recurrence, with the type of recurrence, is necessary to calculate cancer-free intervals and can be used to measure the efficacy of the first course of treatment.

ARM 37.8.1802(1)(x)

The primary payer information is used in financial analysis and as an indicator for quality and outcome analyses. Health care coverage is an important gateway to cancer diagnosis and care. Payer information (classified by type, not by specific carrier, e.g.: uninsured, private insurance, managed care, fee-for-service, Medicaid, Medicare, IHS, etc.), would allow the Montana Central Tumor Registry to evaluate the impact of insurance coverage or lack of coverage on cancer diagnosis and outcome.

ARM 37.8.1802(1)(y)

Occupation and industry information are essential data elements for many epidemiologic investigations of cancer risk factors and causation. Occupation and industry data are used to identify work-related health hazards, serve as an additional measure of socioeconomic status, and identify occupational and industrial groups in which cancer screening activities may be beneficial. Collection of occupation and industry information can be very beneficial when conducting cluster analysis based on work-related groups.

ARM 37.8.1802(1)(z)

These items are essential data elements for many epidemiologic investigations. They are used to determine if alcohol and tobacco use may have caused a higher than average risk of cancer, or to rule out these common exposures in favor of occupational or environmental exposures as potential causes in individuals who have no history of tobacco use. This information would enhance the epidemiologic utility of the registry, in particular in the investigation of occupational or environmental cancers.

5. Concerned persons may submit their data, views, or arguments either orally or in writing at the hearing. Written data, views, or arguments may also be submitted to Gwen Knight, Office of Legal Affairs, Department of Public Health and Human Services, P.O. Box 4210, Helena, Montana, 59604-4210, fax (406) 444-9744; or e-mail dphhslegal@mt.gov, and must be received no later than 5:00 p.m., December 24, 2008.

6. The Office of Legal Affairs, Department of Public Health and Human Services, has been designated to preside over and conduct this hearing.

7. The department maintains a list of interested persons who wish to receive notices of rulemaking actions proposed by this agency. Persons who wish to have their name added to the list shall make a written request that includes the name, e-mail, and mailing address of the person to receive notices and specifies for which

program the person wishes to receive notices. Notices will be sent by e-mail unless a mailing preference is noted in the request. Such written request may be mailed or delivered to the contact person in 5 above or may be made by completing a request form at any rules hearing held by the department.

8. An electronic copy of this Proposal Notice is available through the Secretary of State's web site at <http://sos.mt.gov/ARM/Register>. The Secretary of State strives to make the electronic copy of the Notice conform to the official version of the Notice, as printed in the Montana Administrative Register, but advises all concerned persons that in the event of a discrepancy between the official printed text of the Notice and the electronic version of the Notice, only the official printed text will be considered. In addition, although the Secretary of State works to keep its web site accessible at all times, concerned persons should be aware that the web site may be unavailable during some periods, due to system maintenance or technical problems.

9. The bill sponsor notice requirements of 2-4-302, MCA, do not apply.

/s/ Shannon McDonald
Rule Reviewer

/s/ Hank Hudson for
Joan Miles, Director
Public Health and Human Services

Certified to the Secretary of State November 17, 2008.